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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------------------|----------------------|---------------------------|------------------|
| 10/524,036 | 02/09/2005 | Maharaj K. Sahib | WH-2 | 1841 |
| O M (Sam) Zag | 7590 06/20/2007 2hmout | | EXAM | INER |
| Bio Intellectual Property Services (Bioips) 8509 Kernon Ct Lorton, VA 22079 | | | WOODWARD, CHERIE MICHELLE | |
| | | | ART UNIT | PAPER NUMBER |
| , | | | 1647 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/20/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
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| Office Action Summary | 10/524,036 | SAHIB ET AL. | | | | |
| omee Action Gammary | Examiner | Art Unit | | | | |
| The MAILING DATE of this communication app | Cherie M. Woodward | 1647 | | | | |
| Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | l. lely filed the mailing date of this communication. (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| | Responsive to communication(s) filed on <u>9 February 2005</u> . | | | | | |
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| • | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) <u>1-36</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) <u>1-36</u> are subject to restriction and/or expressions. | vn from consideration. | | | | | |
| Application Papers | | • | | | | |
| 9) The specification is objected to by the Examine | | Evaminer | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | ion is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | · | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P | nte | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11 and 23-28, drawn to a DNA construct and a method of expressing the DNA construct.

Group II, claims 12-22, drawn to a polypeptide.

Group III, claims 29-36, drawn to a method of isolating, purifying, a polypeptide.

- 2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: multiple distinct products and processes of manufacture are claimed (see also MPEP 1850). Pursuant to 37 CFR 1.475, a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and a process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an

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apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

- (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

In the instant case, because multiple products and multiple processes of making the different products are claimed. The DNA construct of Group I is the first claimed product and the polypeptide of Group II is the second product. Accordingly, the main invention (Group I) comprises the first claimed product, which is the DNA construct (claims 1-11, 23-24, and 28) and the method of making the first product (claims 25-27) (see 37 CFR 1.475(d), above; MPEP 1850).

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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> GARY B. NICKOL, PH.D. SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

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